PureSignal Analytics
CASE STUDY

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

ANALYTICS ENABLE POST-HOC SIGNAL REVIEW TO SUPPORT EVIDENCE–BASED DECISION MAKING IN NEUROLOGY PROGRAM

OVERVIEW

A pharmaceutical sponsor partnered with Signant Health to perform post-hoc analysis of their Phase II neurology trial that showed inconsistent efficacy signals. Signant's PureSignal Analytics solution provided detailed investigation of contradictory findings between site and central raters, delivering evidence-based insights to support the sponsor's go/no-go pipeline decision-making.

TRIAL SUMMARY

Study Phase: II

Therapeutic Area: Neurology

Patient Population: Adult

Geographic Scope: 1 country

Number of Sites: 20+

Number of Patients: 90+

Number of COAs: 8

Languages: 1

CHALLENGES

1. The sponsor faced a difficult R&D decision-making challenge when the Phase II trial results showed **contradictory efficacy signals between site and central raters** for key clinical outcome assessments (COAs), including the primary endpoint.

2. While site rater data suggested treatment-placebo separation, central rater assessments failed to demonstrate this effect.

3. This discrepancy created **significant uncertainty around the true treatment effect** and complicated the sponsor's ability to make confident go/no-go decisions for their drug development program.

SOLUTIONS

1. Signant performed a comprehensive **post-hoc analysis** using its **PureSignal Analytics** solution to investigate the source of discrepancy between site and central rater findings.

2. PureSignal Analytics is a **specialized solution** that deploys proprietary algorithms specifically **tailored to study endpoints** to identify and interpret COA administration and scoring issues that might impact the study's ability to **distinguish treatment intervention effects.**

3. Using purpose-built analytics to examine scoring patterns, inter-rater variability, and site-level trends that might **explain the contradictory results,** the solution provided data-driven insights to support the sponsor's development program decision-making.

RESULTS

- The comprehensive post-hoc analysis uncovered **one investigative site with highly problematic data** patterns. When data from this site was **excluded from analysis,** the apparent treatment-placebo separation in the site rater data was no longer evident, aligning with the central rater findings.

- This insight suggested that the original positive signal was driven by data quality issues rather than true treatment effects, leading to Signant's **recommendation of a no-go decision** to the sponsor.

- This analysis demonstrates the value of specialized, clinically-driven endpoint analytics in supporting **evidence-based decisions** and potentially avoiding costly late-phase failures for drug development programs.

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.